

- 919
4. (Once Amended) The system of claim 1 wherein the control system operates the source of microwave energy at frequencies of between 1 GHz to 50 GHz.

REMARKS

Claims 1-14 and 16 are pending. By this Amendment, claims 1, 2, and 4 are amended to correct typographical errors. No narrowing amendments are intended.

The specification and claims have been amended to correct obvious typographical and grammatical errors. No new matter has been introduced.

The Notice to File Corrected Application Papers objected to the drawings requiring the drawings to be labeled in accordance with 37 C.F.R. § 1.84. Amended, informal Figures 1-7 are submitted herewith. The Brief Description of the Drawings section of the specification has been amended to correspond to the drawings. Applicant believes that the informalities asserted by the Notice to File Corrected Application Papers have been cured.

In view of the foregoing, it is submitted that this application is in condition for allowance. Favorable consideration and prompt allowance of the application are respectfully requested.

The Examiner is invited to telephone the undersigned if the Examiner believes it would be useful to advance prosecution.

Respectfully submitted,



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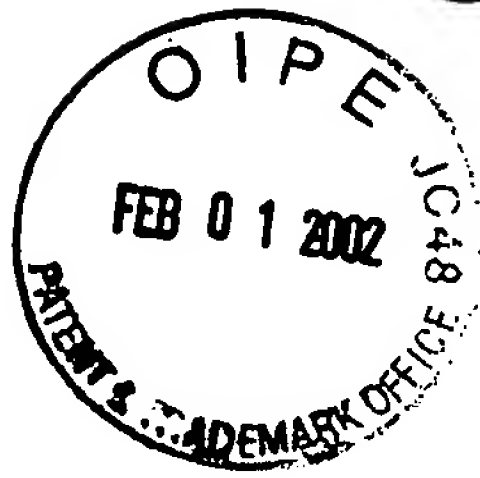
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Application No. 09/897,317

ATTACHMENT
REDLINED AMENDMENT

Specification As Amended

Please substitute the following amended paragraphs and/or sections:

Page 2, lines 13-27

There ha[d]s been relatively little research, however, into the potential impact of the microwave energy itself on the polymerization process for dental prosthetics. The research that has been done has generally focused on the duty cycle used for the microwave oven curing process. The impact on porosity of denture material cured using lower wattage, longer duration microwave cure times (i.e., a lower duty cycle for a longer time) versus higher wattage, shorter duration microwave cure times (i.e., a higher duty cycle for a shorter time) is compared in Alkhatib MB, et al. "Comparison of microwave-polymerized denture base resins," *The International Journal of Prothodontics*, Vol. 3, No. 2, pp. 249-55 (1990). European Patent No. 0 193 514 B1 describes a microwave processing system for dental prosthetics that has a magnetron, a waveguide, a surface radiating antenna, a flask, and a temperature sensor that is inserted in the flask and connected to a regulating processor. The regulating processor limits the temperature in the flask as measured by the temperature sensor by turning on and off the magnetron based on frequency modulation of the duty cycle. Although not used for polymerization of dental articles, U.S. Patent No. 5,645,748 does describe a microwave system for sterilization that controls duty cycle of a microwave oven for the purpose of minimiz[e]ing arcing caused by metallic surgical or dental instruments.

Page 2, lines 28-35 and page 3, lines 1-4

With respect to the second category of dental articles created using polymer materials, dental composites formed of polymer matrix-composites are increasingly being used as an alternative to mercury-containing dental amalgam for aesthetic and restorative dental materials. These kinds of polymer matrix-composites are usually photo polymerizable in that they are cured using some kind of light instead of heat. Generally, the polymer matrix-composite is based on a

photo polymerizable polyfunctional methacrylate compound that can be used alone or as a mixture with monomethacrylates, light sensitive cure initiators pigments and fillers in a mixture with various comonomers such as triethyleneglycol dimethacrylate. Although the half-life of these polymer matrix-composites cured by light is on the order of 5-8 years and therefore they tend to wear out earlier than conventional dental amalgams, the enhanced biofunctionalilty and more pleasing aesthetic qualities of these polymer matrix-composites have gained favor over conventional dental amalgams.

Page 3, lines 5-12

The main deficiencies of polymer composite resins used as dental composites are surface degradation which leads to inadequate wear resistance, polymerization shrinkage and a lack of density. In addition to the problems previously described for dental prosthetics, micro-shrinkage of polymer dental composites produces interfacial gaps on the surface of the composites, which can result[s] in microleakage through the dental composite. The long-term consequence of such microleakage can be bacterial penetration into the tooth that can cause a variety of adverse reactions [in the tooth] such as pulp damage, tooth sensitivity, possible pulpal death and loss of adhesion of the dental composite.

Page 3, lines 25-34

While there are numerous hand-held medical catheter devices that utilize radio frequency and microwave energy to perform ablations and similar heating operations, for example, in the vascular system of a patient, there have been relatively few uses of thermal or electrical energy applied to hand-held dental tools for intra-oral applications. There have been a few hand-held dental probes that utilize an electrically resistive heated tip for diagnosis of dental decay or for melting a sealing material in an intra-oral context as described, for example, in U.S. Patents Nos. 4,527,560 and 5,893,713. U.S. Patent No. 5,421,727 describes the use of radio frequency/microwave energy as part of a hand-held endodontic root canal device to raise the temperature of the interior of the tooth adjacent to the root [canel] canal, thereby tending to disinfect the tooth during the root canal procedure as a result of the increased temperature.

Page 4, lines 1-7

The extra-oral use of microwave energy for the purpose of characterizing dental decay in extracted teeth has been described by N. Hoshi et al in "Application of Microwaves and Millimeter Waves for the Characterization of Teeth for Dental Diagnosis and Treatment," *IEEE Transactions on Microwave Theory and Techniques*, June 1998, Vol. 46, No. 6, pp. 834-38. This study confirmed the higher absorb[a]ency behavior of carious lesions in extracted teeth when irradiated by microwave energy as compared to the lower absorb[a]ency of such microwave energy by healthy enamel and dentin.

Page 5, lines 25-33

BRIEF DESCRIPTION OF THE DRAWINGS

Figure [8] 1 is a partial cross-sectional side view showing the details of a preferred embodiment of the polymer material injector system.

Figure [9] 2 is an isometric view of a hand-held dental tool embodiment of the present invention.

Figures [10-13] 3-6 are various embodiments of antennas for the distal end of the hand-held dental tool embodiment of Figure [9] 2.

Figure [14] 7 is an electrical schematic of the control circuitry for generating the microwave energy in the hand-held dental tool embodiment shown in Figure [9] 2.

Page 6, lines 2-19

Referring now to the various figures, a detailed description of the preferred embodiment of the present invention will be presented. Various complex dielectric permittivity, temperature and distribution pattern studies of microwave heated teeth and simulations of specific absorption rate distribution have been conducted as part of the research into the present invention. The complex permittivity was measured on different types of dental tissues, using extracted teeth, including enamel, dentin and caries. Reflective coefficients have been obtained using a network analyzer. The characteristics of enamel caries and dentin are different. The dielectric loss factor of caries is fairly higher than that of normal healthy parts particularly in the millimetric wave in the frequency between 12 GHz to 25 GHz. When the tooth is exposed to millimetric

microwaves in this range, caries are preferentially heated. Temperature rise can kill the microorganisms in caries. Control and/or extinction of microorganism slows or stops the progress of caries, permitting previously carious tissue to recalcify by biological latent support of the pulp. Temperature distribution measurement with microwave[s] heating reveals that the temperature of caries is higher than that of normal tooth tissue. These properties are used with the provisions of this invention for the diagnostic and treatment of teeth having caries and subsequent internal heat conditioning and/or curing of provided dental restorative materials. When dielectric loss factor is higher, the absorption of microwave is better and local temperature is higher. Microwave energy heats by radiation and is able to penetrate through various substances including desiccated tissue and thus can create an addressed effect.

Page 6, lines 20-22

To understand the details on which the preferred embodiment is based, it is helpful to understand how microwave energy is generated and absorbed. The microwave energy absorbed by a given dental material[s] is governed by the following equation:

Page 7, lines 4-33

In one embodiment as shown in Figure [14] 7, a system of caries control in a non - invasive atraumatic way, without surgical burs entry and with a reduced risk and necessity of exposing the dental pulp organ comprise, a hand-held microwave applicator with a sufficient microwave power delivery capability is provided to heat the dental tissues or restorative materials. The electronic circuit diagram of Figure [14] 7 is designed to suit small microwave generators such as an oscillation source coupled with a RF power amplifier or impatt diodes or similar solid state or transistorized microwave emitters with an output power of about 2 to 5 watts which requires usually an electrical voltage of about 60 DC. The bias voltage is applied through a high impedance line (56) in order to limit the perturbation of electromagnetic signals. A power supply module is provided with a current and voltage limiting means to permit the polarization of the impatt diode in the specific limits with a resonant circuit (57), such as a 50 ohms line, having a length preferably equal to the half of the length of the selected frequency. The length of the line may be calculated with the following equation: $L = 3 \times 10^8 / 2f \quad c_{ff}^{1/2}$.

One end of the "resonator" is connected to the impatt diode (58) and the other end of it is coupled (59) to a transmission line including an isolator (60) to provide isolation of the microwave source from the rest of the circuit in order to avoid frequency variations, caused by a mismatch of the output (61). A coupler (62) having a coupling of about -15 dB permit a sampling of the signal emitted by the microwave generator in order to measure the incident and reflected power levels. The couplers should be perfectly matched at both extremities to permit precise measurements. Matching circuit (63) at the input and the output as well as load resistors permit achievement of an adaptation at each end[s], equal or better than -15dB. Detecting diodes (64) rectify the radio frequencies signal in order to convert the power to a dc voltage which can advantageously be subsequently transmitted to a micro controller or a "ADC" analog digital converter which converts this voltage to a digital signal for an appropriate processing of the acquired information and the precise monitoring and the control of the microwave's energy delivered to the dental target. The controller is a means of setting the power level, exposure cycles, processing modes, and may also be used in the selection of the frequency of microwave generation. As shown in Figure [9] 2, the control of the microwave source is preferably made by a selector (65), located on the device, allowing the operator to set different power levels and modes. Between the tip antenna and the microwave source or amplifier, a shielded cable (66) or wave guide, as short as possible is used to operatively transmit the microwave power to the head antenna.

Page 8, lines 1-34

A suitable connector preferably permits the interchange of different provided head antennas to match different applications and enhance energy transmission and deposition on the dental target. A means of electrical supply (67), such as a shielded cable, connects the mobile applicator to the power supply. The hand-held applicator may be equipped with a water cooling system (68) and a digital display (69).

One head antenna (70), as shown in Figure [11] 4, is provided for therapeutic purposes to target teeth and treat, heat or detect dental caries, and is made of a highly conductive metal such as copper, platinum or gold, plated or not, having the format of a rectangular or a loop-shaped

band, of which one end is connected to the inner and the outer conductors of the transmission line.

One provided monopole head antenna has the form of an I as shown in Figure [12] 5. This applicator is made for example by stripping the outer jacket and the outer conductor of a coaxial shielded cable, the inner conductor and dielectric (Teflon) constitute the applicator. To increase the directivity of the radiating microwave energy, a loaded I-applicator (71) having an increased forwarding effect may be made by placing a platinum ring over the outer conductor of the coaxial cable and soldering a platinum rod on the inner conductor of the antenna.

Another provided head antenna (72), as shown in Figure [13] 6, is made of a microstrip, which may be made of miscible polymeric or other conductive materials, having the format, for example, of a square metal skin is positioned on a dielectric substrate with a ground plane on its back.

An electrically shielded temperature probe may be embedded in the head of the hand-held applicator antenna to provide a means of monitoring the temperature of the heated target for judging the efficiency of tissue heating and to avoid sudden temperature rises.

The provided head antenna designs help in achieving good impedance matching and effective delivery of microwave for internal heat conditioning of dental targets. As shown in Figure [10] 3, a means of safely containing any leakage of microwave energy close to the irradiation space can be used such as the disclosed head antenna choke (73), made of microwave absorbing materials.

Preferably, the antennas are made with a portion that is strong and flexible enough to be used as a positioning and compression tool for the pasty resin matrix for the dental composite. The loop and patch antenna may preferably carry negative dental molds to aid in the formation of the dental composite. Alternatively, a miniaturized version of a manual resin injector, such as previously described in connection with Figure [8] 1, may be provided to deliver the pasty resin matrix for the dental composite as part of the hand-held tool. While the hand-held tool is preferably used in an intra-oral application with dental composites, it will be recognized that the hand-held tool can also be used in the dental office, for example, to accomplish repairs or welds of dental prosthetics devices as well.

Page 9, lines 1-7

In one embodiment as shown in Figure [8] 1, an economic manual fluid resin pressurization and injection device (46) is provided to remove the need of being connected to an external pressurized fluid source. A mechanical force accumulator such as a spring (47) is compressed by turning the internally threaded cylinder (48) while holding the device handle (49). A force boosting piston (50) is especially useful for molding and filling of composite curable dental materials. The injection nozzle and the piston acts as previously described. This embodiment can be miniaturized and employed with the hand-held intra-oral microwave applicator.

Page 10, lines 10-22

The microwave sensitive initiators in accordance with the invention include[s] benzoyl and peroxide, dilauroyl peroxide up to 2,5%. The polymerization accelerator in accordance with the invention is a quaternary ammonium chloride, which is easily soluble in the methacrylate monomers and reacts with barbituric acid derivatives. A preferred compound[s are] is the quaternary ammonium with an alkyl of 1 to 20 carbons, such as, dodecyltrimethylammonium. These quaternary ammonium chlorides may be added in alone or in admixture from 0,09 to 1,5 %. The cross-linking agent, in accordance with the provided microwave hardening material compositions, is a polyfunctional monomer wherein at least two carbon-carbon double bonds, such as 1,3-butanediol dimethacrylate, 1,4-butanediol dimethacrylate, 1,4-butanediol divinyl ether, di(ethylene glycol) dimethacrylate, di(ethylene glycol) divinyl ether, pentaerythritol diacrylate monostearate, ethylene glycol dimethacrylate, trimethylolpropane trimethacrylate, pentaerythritol triacrylate, pentaerythritol tetraacrylate, trimethylolpropane triacrylate. The cross-linking agents may be used alone or in admixture.

Page 11, lines 3-8

The composition for a one component microwavable curable material system in accordance with this invention is approximately the same as the one for the two component materials with some variations mainly in the initiation system. Preferred initiators, for a one component dental composition for denture or such, need to be thermally stable at room or higher

temperatures such as 50°C and initiate polymerization at higher temperatures such as benzopinacol, tert-butylperbenzoate, and 2,2'-dichlorobenzopinacol.

Page 11, lines 23-28

Inorganic and organic fillers may be added into the compositions of one or two components' denture base. Useful inorganic fillers include glass, metal ceramics, silicon dioxide in powdery or fiber format, which are preferably silanized with a coupling agent, such as 3-methacryloxypropyltrimethoxy. Organic fillers include splinter or bead polymers of high molecular weight-, or fibers such as aramide fibers, polyacrylate fibers, polyamide fibers and polyacrylonitrile fibers. Organic fillers may be used alone or mixed with inorganic fillers.

Page 11, lines 29-30 and page 12, lines 1-2

Thermoplastic compounds such as poly functional methacrylate, polycarbonate, polysulfone, fluoropolymers, elastomers, polyurethanes, impression compound, wax, gutta percha, polycaprolactone and mixtures of thermoset and thermoplastics are advantageously heat processed with the provided method and permit dental rehabilitation.

Page 12, lines 3-14

Microwave absorbing substances can advantageously be incorporated into disclosed thermoplastic and thermohardening material compositions; to decrease internal heat generation of compositions which does not have sufficient dielectrical loss when microwaved nor do[es] they have sufficient heatability for a desired speed of heating. These microwave absorb[a]ents are also useful when the employed polymeric material has only a low microwave absorption behavior at low temperatures such as many thermoplastic polymers including polycarbonate and also for substantially increasing the speed and the addressability such as in welding and joining functions. These absorbers may be powdery, hollowed, coated and comprise ferromagnetics, metallic oxides or special[i]ty ceramics. Microwave absorb[a]ent materials and/or sterilants can be advantageously utilized with the intra-oral embodiment of the present invention to increase the speed and addressability of heating the dental composite and to increase the effectiveness of the sterilization of the targeted caries.

Page 12, lines 15-16

The following tables set forth several examples in accordance with the various aspects of the present invention. All ratios for materials are expressed in weight.

In the Claims

1. (Once Amended) A microwave dental system comprising:
 - a hand-held dental tool including:
 - an antenna positioned at a distal end of the tool and configured to be selectively positioned within a mouth of a patient adjacent at least one exterior surface of a tooth; and
 - a waveguide connected to the antenna;
 - a source of microwave energy operably coupled to the waveguide, including a control system for controlling delivery of microwave energy to the waveguide[.] such that the dental tool delivers microwave energy to the at least one exterior surface of the tooth.
2. (Once Amended) The microwave dental system of claim 1 wherein the control system controls the source of microwave energy to deliver less than 10 W to the antenna.
4. (Once Amended) The system of claim 1 wherein the control system operates the source of microwave energy at frequencies of between 1 GHz to 50 GHz.